

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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PURDUE PHARMA PRODUCTS L.P.,	)	
NAPP PHARMACEUTICAL GROUP LTD.,	)	
BIOVAIL LABORATORIES INTERNATIONAL,	)	
SRL, and ORTHO-MCNEIL, INC.,	)	
	)	
Plaintiffs/Counterclaim-defendants,	)	Civil Action No. 07-255-JJF
	)	Civil Action No. 07-414-JJF
v.	)	Civil Action No. 07-666-JJF
PAR PHARMACEUTICAL, INC. and	)	
PAR PHARMACEUTICAL COMPANIES, INC.,	)	
Defendants/Counterclaim-plaintiffs.	)	
	)	

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**STIPULATED PROTECTIVE ORDER**

Pursuant to Fed. R. Civ. P. 26(c), Purdue Pharma Products L.P., Napp Pharmaceutical Group Ltd. (collectively “Purdue”), Biovail Laboratories International, SRL (“Biovail”), and Ortho-McNeil, Inc. (“Ortho”) (collectively “Plaintiffs”), and Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively “Par” or “Defendants”) (hereinafter individually referred to as a “party” or collectively as “the parties”) stipulate that good cause exists for entry of a protective order to prevent unauthorized disclosure and use of the parties’ trade secrets and other confidential information during and after the course of this litigation. Accordingly, IT IS HEREBY ORDERED THAT:

1. **Definitions.** As used in this Stipulated Protective Order, these terms have the following meanings:

- (a) “Confidential Information” means information designated in accordance with Paragraph 2.
- (b) “Highly Confidential Information” is the subset of Confidential Information designated in accordance with Paragraph 3.
- (c) “Materials” includes all documents, transcripts, records and things (in oral, written or electronic forms) within the scope of Federal Rule of Civil Procedure 34, any form of discovery contemplated under Rules 26 through 36 of the Federal Rules of Civil Procedure, hearing and trial transcripts, any type of evidence, and any other information furnished, directly or indirectly, by or on behalf of any party to this litigation or any third party.
- (d) “Written Assurance” means an executed document in the form attached as Exhibit A.
- (e) “Requesting party” means the party that seeks the disclosure of Confidential Information.
- (f) “Producing party” means the party that owns or otherwise controls the Confidential Information requested by the requesting party.

2. **“Confidential Information.”** “Confidential Information” shall mean material that a party claims in good faith contains or discloses information relating to, referencing or pertaining to trade secrets or other confidential or proprietary research, development, or commercial information within the meaning of Federal Rule of Civil Procedure 26(c)(7).

3.     **“Highly Confidential Information.”** “Highly Confidential Information” shall mean Confidential Information that is of such sensitivity that a party reasonably believes that its disclosure to the adversary could harm its competitive position in business, such as customer, licensee, supplier and vendor information, financial or marketing information and forecasts (including past information indicative of current practices), business plans or competitive strategies, information on the producing party’s products currently in development and not yet commercially released, communications and filings with FDA, clinical study reports, pending and draft patent applications, and documents and other materials that refer to the manufacture or production of tramadol dosage forms.

4.     **Designation of Confidential Information.** Confidential Information may be designated as subject to this Protective Order as follows:

- (a)     With respect to documents or copies provided by one party to the other, by marking the initial page and the page or pages on which any Confidential Information appears with the legend “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL.” In the case of computer medium, the marking shall be placed on the medium and its label and/or cover. To the extent practical, the “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” designation shall be placed near the Bates number.
- (b)     In lieu of marking the original of a document that contains Confidential Information prior to inspection, counsel for the producing party may orally or in writing designate documents being produced for inspection as containing Confidential Information, thereby making them subject to this Order; however, any copies of such documents must be marked by the

producing party in accordance with subparagraph (a) at the time copies are provided.

- (c) Testimony or information disclosed at a deposition may be designated by a party as Confidential Information by indicating on the record at the deposition the specific testimony that contains Confidential Information that is to be made subject to the provisions of this Order. Whenever possible, the stenographic reporter shall be requested to separate those portions of the transcript containing Confidential Information or Highly Confidential Information and separately bind them from each other and from the non-confidential portions. Alternatively, a party may designate testimony or information disclosed at a deposition as Confidential Information by notifying the other parties, in writing, within thirty (30) calendar days of receipt of the transcript of the deposition, of the specific pages and lines of the transcript that are to be designated as Confidential Information. Each party shall attach a copy of such written statement to the face of the transcript and each copy thereof in its possession, custody, or control. Whether or not designation is made at the time of a deposition, all depositions shall be treated as Highly Confidential Information from the taking of the deposition until thirty (30) calendar days after receipt of the transcript, or until receipt of the notice referred to in this subparagraph, whichever occurs sooner.
- (d) In the case of responses to interrogatories, other discovery requests or responses, affidavits, briefs, memoranda, or other papers filed with the

Court, information contained therein may be designated as Confidential Information by prominently marking such paper with the legend “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL.”

Further, any document or object may be filed with the Clerk’s Office and placed under seal by submitting it with a cover sheet containing (a) the caption for this action, (b) the title or description of the document or object; and (c) the words “CONFIDENTIAL—FILED UNDER SEAL PURSUANT TO PROTECTIVE ORDER.” Any document or object submitted with such a cover sheet will be maintained under seal by the Clerk’s Office.

- (e) If a document has more than one designation, the more restrictive designation applies.
- (f) The inadvertent or unintentional failure by a producing party to designate specific documents or materials as containing Confidential Information shall not be deemed a waiver in whole or in part of a party’s claim of confidentiality as to such documents or materials. Upon notice to the receiving party of such failure to designate, the receiving party shall cooperate to restore the confidentiality of the inadvertently disclosed information, without prejudice.

#### **5. Access to Confidential Information.**

- (a) Except upon the prior written consent of the producing party, or upon further Order of this Court, Confidential Information or Highly Confidential Information shall be treated strictly in accordance with the

provisions of this Protective Order and may be used or disclosed only as specified in this Protective Order.

(b) Access to information marked CONFIDENTIAL shall be limited to:

(i) Outside counsel and their employees whose duties and responsibilities require access to such materials. The current counsel of record are listed below:

Frommer Lawrence & Haug LLP  
745 Fifth Avenue  
New York, New York 10151

Ropes & Gray LLP  
1211 Avenue of Americas  
New York, New York 10036

Ropes & Gray LLP  
525 University Avenue  
Suite 300  
Palo Alto, CA 94301

Connolly Bove Lodge and Hutz, LLP  
1007 N. Orange St.  
P.O. Box 2207  
Wilmington, DE 19899

Connolly Bove Lodge and Hutz, LLP  
1875 Eye Street, NW  
Suite 1100  
Washington, DC 20006

Bayard, P.A.  
222 Delaware Avenue, Suite 900  
Wilmington, DE 19899-5130

Richards, Layton & Finger  
One Rodney Square  
P.O. Box 551  
Wilmington, DE 19899

Morris, Nichols, Arsht & Tunnell LLP  
1201 N. Market St.  
P.O. Box 1347  
Wilmington, DE 19899

- (ii) In-house attorneys for each of Purdue, Biovail, Ortho, and Par who have responsibility for maintaining, defending or evaluating this litigation, and their employees whose duties and responsibilities require access to such materials.
- (iii) Outside experts and consultants and their staffs who are employed, retained or otherwise consulted by outside counsel to assist in any way in the preparation and trial of this litigation. For purposes of this Protective Order, the phrase "outside experts and consultants" shall not include any officer, director or employee of any party.
- (iv) Witnesses in any deposition or other proceeding of this action who
  - (1) at the time of such proceeding, are current employees of the producing party, (2) are the author or recipient of the information marked Confidential, (3) based on evidence, are reasonably believed to have had access to the "Confidential Information" in the past, or (4) the producing party consents to such disclosure.
- (v) Vendors retained by or for the parties for preparing audiovisual aids, *e.g.*, exhibits, models, graphics, and video-tapes for use in the court room, as well as their staff, stenographic, and clerical employees whose duties and responsibilities require access to such materials, who are not current employees of any party to this litigation or of any direct competitor of any party to this litigation.

- (vi) Outside document copying services and/or document coding or computerization services for the specific and limited purpose of providing photocopies or document coding or computerization services, who agree to be bound by this protective order.
  - (vii) The Court, Court personnel and stenographic and video reporters engaged in proceedings incident to this action.
- (c) Access to information marked HIGHLY CONFIDENTIAL shall be limited to:
- (i) Persons specified in paragraphs 5(b)(i), 5(b)(iii), 5(b)(iv), 5(b)(v), 5(b)(vi), and 5(b)(vii).
  - (ii) Up to two (2) specified in-house attorneys for each of Purdue, Biovail, Ortho, and Par who have responsibility for maintaining, defending or evaluating this litigation (but who do not have direct responsibility for prosecuting patent applications related to compounds, methods or compositions used to alleviate pain) and who do not have competitive decision-making responsibilities (*i.e.*, who are not directly involved in decisions regarding pricing or marketing and who do not directly communicate with purchasers and suppliers about non-legal issues) with respect to any controlled-release tramadol product, and their employees whose duties and responsibilities require access to such materials. Purdue's attorneys are Richard Silbert (Associate General Counsel) and Rachel Kreppel (Counsel). Biovail's attorney is

Charles R. Krikorian (Vice President and Senior Legal Counsel). Ortho's attorneys are Harman Avery Grossman (Assistant General Counsel) and Theodore B. Van Itallie, Jr. (Associate General Counsel). Par's attorneys are Thomas J. Haughey (Executive Vice President – General Counsel) and Lawrence M. Brown, Ph.D. (Patent Counsel). Purdue, Biovail, Ortho, and Par may, as necessary, request substitution or addition of other lawyers without a role in prosecution or competitive decision-making for controlled-release tramadol products, and consent will not be unreasonably withheld.

- (d) As a condition precedent to disclosure of Confidential Information or Highly Confidential Information to any in-house attorney, outside expert or consultant, or vendor described in paragraphs 5(b) and 5(c), he or she must sign the Written Assurance attached hereto as Exhibit A.

**6. Designation of Experts and Consultants.** For each independent expert and consultant who executes a Written Assurance, counsel who retained the independent expert and consultant shall forward by facsimile a copy of the executed assurance and a current curriculum vitae of the person to counsel for the other parties at least seven (7) calendar days prior to the proposed disclosure of Confidential Information.

Any party may object to the proposed disclosure to the expert within seven (7) calendar days after receipt of the executed assurance. Opposing counsel shall make a good-faith effort to reach an agreement regarding the proposed disclosure to the expert. If an agreement cannot be reached, the objecting party shall make an appropriate motion within ten (10) calendar

days after the objection is made. The burden shall be on the objecting party to show the Court why the disclosure should not be made.

If an objection is made, no Confidential Information shall be made available to the particular person until after the Court rules that disclosure can be made, so long as the objection is followed by a timely motion.

**7. Challenge to designation.**

- (a) The signing of this Protective Order or failure of a party, at the time it receives discovery materials designated as Confidential Information or Highly Confidential Information to challenge or object to the Confidential Information or Highly Confidential Information designation shall not be deemed a waiver of its right to challenge or object to the designations at any later time.
- (b) Any party may at any time challenge the designation of any discovery materials as Confidential Information or Highly Confidential Information and may request permission to use or disclose information with the Confidential Information or Highly Confidential Information designation other than as permitted, pursuant to this paragraph by serving (by facsimile transmission) a written request upon counsel for the producing party before the date of the proposed disclosure and by providing telephonic notice of such request on the same date as the facsimile is transmitted. Such request shall specifically identify the Confidential Information, including production number, sought to be so disclosed and

the name, title and function of the person to whom such disclosure is desired to be made.

- (c) The producing party shall thereafter respond to the request in writing within ten (10) calendar days after receipt of same. Absent good cause shown, a failure to respond within such time shall constitute consent to the request. If, where consent has been withheld, the parties are subsequently unable to agree on the terms and conditions of the requested disclosure, the matter may be submitted to the Court for resolution by the party seeking disclosure. Such disclosure shall be postponed until a ruling has been obtained from the Court.

**8. Use of Confidential Information.**

- (a) Confidential Information obtained from a producing party pursuant to pretrial discovery in this action, including any notes, memoranda or other similar documents relating thereto may be used and disclosed only for purposes of these actions, i.e., Civil Action Nos. 07-255-JJF, 07-414-JJF and 07-666-JJF, and any appeals therefrom. No party or person shall make any other use of any such Confidential Information, including but not limited to use for commercial or competitive purposes or use in any other legal proceeding, except as permitted by order of the Court. No party or person shall make available, disclose or summarize Confidential Information to any persons, including the parties, other than to qualified persons under the terms of this Protective Order. Confidential Information

shall be maintained by the receiving party under the overall supervision of outside counsel.

- (b) Nothing in this Protective Order shall prevent a party from using Confidential Information at trial or during a hearing. However, the party using Confidential Information must request (i) that the portion of the proceeding where use is made be *in camera* or protected from public disclosure to the maximum extent practicable and (ii) that the transcript of that portion of the proceeding be maintained under seal in accordance with paragraph 4(d) hereof, with access thereto limited to persons entitled to access under this Protective Order.
- (c) Any person in possession of Confidential Information shall exercise reasonably appropriate care with regard to the storage, custody and use of such Confidential Information in order to ensure that the confidential nature of the same is maintained.
- (d) If Confidential Information is disclosed to anyone other than in a manner authorized by this Protective Order, the party responsible for such disclosure must immediately bring all pertinent facts relating to such disclosure to the attention of the producing party and make every reasonable effort to retrieve such Confidential Information and to prevent further disclosure.
- (e) Nothing in this Protective Order shall be construed (a) as preventing a party from using or continuing to use any information that is or becomes publicly known through no unauthorized act or omission of such party, or

(b) as preventing a party from using or continuing to use any information that is or becomes known to it if such information was or is lawfully obtained by such party other than through discovery of the producing party. Should a dispute arise as to any specific information or material, the party claiming that such information or material is or was publicly known or was lawfully obtained other than through discovery of the producing party shall have the burden of proving its claim.

9. Entering into, agreeing to, producing and/or receiving Confidential Information or otherwise complying with the terms of the Protective Order shall not:

- (a) Operate as an admission by any party that any discovery material designated as Confidential Information contains or reflects trade secrets or any other type of confidential or proprietary information entitled to protection under applicable law;
- (b) Prejudice in any way the rights of any party to object to the production of documents it considers not subject to discovery, or operate as an admission to any party that the restrictions and procedures set forth herein constitute adequate protection for any particular information deemed by any party to be Confidential Information;
- (c) Prejudice in any way the rights of any party to object to the authenticity or admissibility into evidence of any document, testimony or the evidence subject to this Protective Order;

- (d) Prejudice in any way the rights of any party to seek a determination by the Court whether any discovery material or Confidential Information should be subject to the terms of this Protective Order;
- (e) Prejudice in any way the rights of any party to petition the Court for a further protective order relating to any purportedly Confidential Information;
- (f) Prejudice in any way the rights of any party to petition the Court for permission to disclose or use particular Confidential Information more broadly than would otherwise be permitted by the terms of this Protective Order; or
- (g) Prevent any Designating Party from agreeing to alter or waive the provisions or protection provided for herein with respect to any particular discovery material designated as Confidential Information by that party.
- (h) Nothing in this Protective Order shall prevent disclosure beyond the terms of this Order if the producing party consents in writing to such disclosure, or if the Court, after notice to all affected parties, orders such disclosure.

**10. Inadvertent and Unintentional Disclosure.**

- (a) Furnishing of documents (including physical objects) to the receiving party; using documents in depositions, pleadings or any written discovery; or disclosing documents to the Court shall not constitute a waiver of the attorney-client privilege or work product immunity with respect to any document or physical object so furnished, if within ten (10) calendar days after learning of the inadvertent and/or unintentional production, the

producing party designates any such documents as within either the attorney-client privilege or work product immunity and requests return of any such documents to the producing party.

- (b) Upon request by the producing party for return of any such documents designated as within either the attorney-client privilege or work product immunity, the receiving party immediately shall return to the producing party all paper copies of such documents, and/or shall immediately confirm in writing that all electronic copies of the documents have been deleted from electronic records and all paper copies of the documents have been destroyed.
- (c) Nothing herein shall prevent the receiving party from challenging the propriety of the attorney-client privilege or work product immunity designation by filing an appropriate motion with the Court. In such a motion, the burden of establishing privilege shall remain on the party asserting the privilege.

**11. Applicability after Conclusion of Proceedings.** All provisions of this Protective Order restricting the use of information obtained during discovery shall continue to be binding on the parties and all persons who have received information under this Protective Order, after the conclusion of this action, including all appeals until further Order of the Court, unless the parties otherwise agree in writing.

- (a) Within sixty (60) calendar days after the conclusion of these actions, all documents, objects, and other materials produced or designated as Confidential Information, including extracts and summaries thereof, and

all reproductions thereof, shall be returned to the producing party or shall be destroyed, at the option of counsel in possession of such copies, except that outside counsel for each party may maintain in its files one copy of (i) each pleading filed with the Court, (ii) each deposition transcript together with the exhibits marked at the deposition, (iii) one copy of trial or hearing transcripts along with one copy of any exhibit used at trial, (iv) one copy of each piece of correspondence, and documents constituting work product that were internally generated based upon or which include Confidential Information. If the materials are destroyed, counsel responsible for the destruction shall within seven (7) calendar days of such destruction certify to counsel for the producing party that destruction has taken place.

- (b) In the event that outside counsel maintains such documents, it shall not disclose material maintaining any type of Confidential Information to another party or third party absent subpoena or court order. Upon receipt of any subpoena for such information, the party receiving the subpoena shall immediately notify outside counsel for the producing party of the subpoena so that the latter may protect its interests.
- (c) Insofar as the provisions of this and any other Order entered in this action restrict the communication and use of information, such Order(s) shall continue to be binding after the conclusion of this litigation except (i) that there shall be no restriction on documents that are used as exhibits in Court (unless such exhibits were filed under seal); and (ii) that a party may

seek the written permission of the producing party or further order of the Court with respect to dissolution or modification of any such Order(s).

12. This Protective Order has been agreed to by the parties to facilitate discovery and the production of relevant evidence in this action. Neither the agreement of the parties, nor the designation of any information, document, or the like as Confidential Information, nor the failure to make such designation shall constitute evidence with respect to any issue in this action.

13. **Third Parties.** The terms of this Protective Order shall be applicable to any third party who produces information that is designated by such third party as Confidential Information pursuant to this Protective Order. Nothing in this paragraph permits a party to designate as Confidential Information any information produced by a third party which that third party did not itself designate as Confidential Information, unless the third party has confidential information of a party that it is legally obligated to maintain as confidential.

14. Nothing in this Protective Order shall prejudice the right of any party, or any third party, to seek relief from the Court, upon good cause shown, from any of the restrictions provided above or to impose additional restrictions on the disclosure of any information or material.

15. This Court shall retain jurisdiction over the parties and this Protective Order for the purposes of compliance with and enforcement of its terms, and the final termination of these actions shall not terminate this Protective Order or its terms.

16. Until such time as this Protective Order has been entered by the Court, the parties agree that upon execution by the parties, it will be treated as though it had been "So Ordered."

We hereby stipulate to the entry of the foregoing Protective Order:

RICHARDS, LAYTON & FINGER

/s/ Steven J. Fineman  
Frederick L. Cottrell, III (#2555)  
Steven J. Fineman (#4025)  
[Fineman@rlf.com](mailto:Fineman@rlf.com)  
One Rodney Square  
Wilmington, Delaware 19899  
(302) 651-7700  
*Attorneys for Defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc.*

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II  
Jack B. Blumenfeld (#1014)  
Rodger D. Smith II (#3778)  
[rsmith@mnat.com](mailto:rsmith@mnat.com)  
1201 N. Market Street  
Wilmington, DE 19899-1347  
(302) 658-9200  
*Attorneys for Plaintiffs Purdue Pharma Products L.P. and Napp Pharmaceutical Group Ltd.*

CONNOLLY BOVE LODGE AND HUTZ, LLP

/s/ Mary W. Bourke  
Mary W. Bourke (#2356)  
[MBourke@cblh.com](mailto:MBourke@cblh.com)  
1007 N. Orange St.  
P.O. Box 2207  
Wilmington, DE 19899  
(302) 658-9141  
*Attorneys for Plaintiff Ortho-McNeil, Inc.*

BAYARD, P.A.

/s/ Richard D. Kirk \_\_\_\_\_

Richard D. Kirk (#922)  
[rkirk@bayardfirm.com](mailto:rkirk@bayardfirm.com)  
222 Delaware Avenue, Suite 900  
Wilmington, DE 19899-5130  
(302) 655-5000  
*Attorneys for Plaintiff Biovail Laboratories International, SRL*

SO ORDERED this \_\_\_\_ day of \_\_\_\_\_, 2008.

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Joseph J. Farnan  
United States District Court Judge

**EXHIBIT A**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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PURDUE PHARMA PRODUCTS L.P.,	)	
NAPP PHARMACEUTICAL GROUP LTD.,	)	
BIOVAIL LABORATORIES INTERNATIONAL,	)	
SRL, and ORTHO-MCNEIL, INC.,	)	
	)	
Plaintiffs/Counterclaim-defendants,	)	Civil Action No. 07-255-JJF
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v.	)	Civil Action No. 07-666-JJF
	)	
PAR PHARMACEUTICAL, INC. and	)	
PAR PHARMACEUTICAL COMPANIES, INC.,	)	
	)	
Defendants/Counterclaim-plaintiffs.)		

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**WRITTEN ASSURANCE**

The undersigned hereby acknowledges that (s)he has read the Protective Order entered on \_\_\_\_\_, in the above-captioned action, and understands the terms thereof, and agrees, upon threat of penalty of contempt, to be bound by such terms of each paragraph of the Protective Order.

In particular, the undersigned understands that the terms of said Protective Order obligate him/her to use Confidential Information or Highly Confidential Information solely for the purposes of this litigation and to not disclose any such Confidential Information or Highly Confidential Information to any other person, firm or entity, except that there will be no restriction on documents that are used as exhibits in Court, unless such exhibits were filed under seal, and there will be no restriction on information disclosed in open Court, unless the Courtroom is sealed at the time of such disclosure.

Further, for the purpose of enforcing this Confidentiality Agreement, the undersigned hereby subjects himself/herself to the jurisdiction of this Court.

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Date

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Signature

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Printed Name